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Baker Donelson Bearman, Caldwell & Berkowitz, PC
920 Massachusetts Ave, NW
Suite 900
Washington, DC 20001

EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/726,880
Filing Date: November 30, 2000
Appellant(s): CHEN ET AL.

Shazi Jiang
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/16/11 appealing from the Office action mailed 6/22/11.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

3-14, 17, 28-31 and 33-36

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,952,395	Lorant	9-1999
5,968,251	Auweter et al.	10-1999
2,756,177	Cannalonga	7-1956
EP 0937412 A1	Stein et al.	8-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. Claims 3-14, 17, 28-31 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over either US 5,968,251 to Auweter (submitted on PTO 1449 of 12-29-08) in view of US 5952395 to Lorant et al or Auweter and EP 937412 ('412) in view of in view of US 5952395 to Lorant et al.

Auweter teaches cold water dispersible powders comprising fat soluble vitamins such as carotenoids prepared by the method described in abstract and col. 2, L 27-46. For the protective colloids, Auweter teaches the claimed proteins such as fish gelatin, vegetable proteins, and also gum such as gum arabic (col. 4, L 40-53). Auweter teaches a 0.5-20% carotenoids and 10-50% by weight of a protective colloid (col. 4, L

53-59). These amounts overlap with the amounts of claims 36 and 37. For the vitamins of claims 10-11, Auweter teaches carotenoids esters and not the claimed vitamin esters. Auweter teaches the carotenoids powders for food compositions but not tablet preparations (instant claim 17). However, preparing an appropriate form of vitamin A powder depending on the food preparation would have been within the scope of a skilled artisan because Auweter teaches the preparation of carotenoids (vitamin A constituent). Auweter does not exemplify any compositions with the claimed gums or proteins. Auweter teaches particles of 200 nm size (col. 3, L 51-56) but not the claimed 80 -120 nm.

EP '412 teaches finely divided pulverous carotenoids preparations formed by suspending the active ingredient in an organic solvent, feeding the suspension to a heat exchanger, rapidly mixing with a swellable colloid. EP teaches the particle size such as 213 nm, 225 nm or 400 nm. Among the colloids, EP teaches gelatin, starch, gums, pectin etc. (col. 3, L 1-7). EP does not readily envisage the claimed particle size of 80-120 nm.

Lorant teaches gelled ultrafine oil-in-water emulsions having a particle size of 50 nm to 1000 nm (abstract). Lorant teaches that ultrafine particle oil-in-water emulsion pose stability problems, become extremely fluid, require specific oils to avoid separation and also bluish in appearance. Therefore in order to overcome the problems, Lorant suggests adding a gelling polymer to the aqueous phase and further suggests incorporating cosmetically active agents (see entire col. 2). Lorant teaches nanoparticle sizes in the range of 30-200 nm (col. 4, l 34-43). Even though Lorant is

directed to a cosmetic composition and to an oil-in-water emulsion and not the claimed dry powder of dispersed vitamin in a polymer matrix, the teachings of Lorant are analogous to that of EP because Lorant is also directed preparing fine particles of oily material emulsified in a continuous medium containing a gelling agent (which can be equated to the claimed polymer) and hence it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the powders of Auweter in nanoparticle size ranges and further a skilled artisan would have the knowledge of preparing the particles in the size ranges as low as 30-200 nm (of Lorant) that includes the claimed particle sizes. Lorant teaches that the smaller particle size, lesser the surface tension and higher the stability (see col. 1, l 26-32). According to Lorant reducing the particle size of the oily phase can reduces the need for high concentrations of emulsifying agents and suggests a particle size of 50-1000 nm. Further, it would have been obvious for a skilled artisan to modify the teachings of Auweter by incorporating colloids such as polysaccharide gums or proteins such as those taught by Auweter or EP because both references are directed to preparing the claimed powders and further EP suggests colloids such as gelatin and gums as effective in preparing vitamin powder preparations.

2. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,968,251 to Auweter (submitted on PTO 1449 of 12-29-08) in view of US 5952395 to Lorant et al and US 2,756,177 to Cannalonga or Auweter and EP 937412 ('412) in view of US 5952395 to Lorant et al and US 2,756,177 to Cannalonga.

Auweter teaches cold water dispersible powders comprising fat soluble vitamins such as carotenoids prepared by the method described in abstract and col. 2, L 27-46. For the protective colloids, Auweter teaches the claimed proteins such as fish gelatin, vegetable proteins, and also gum such as gum arabic (col. 4, L 40-53). Auweter teaches a 0.5-20% carotenoids and 10-50% by weight of a protective colloid (col. 4, L 53-59). These amounts overlap with the amounts of claims 36 and 37. For the vitamins of claims 10-11, Auweter teaches carotenoids esters and not the claimed vitamin esters. Auweter teaches the carotenoids powders for food compositions but not tablet preparations (instant claim 17). However, preparing an appropriate form of vitamin A powder depending on the food preparation would have been within the scope of a skilled artisan because Auweter teaches the preparation of carotenoids (vitamin A constituent). Auweter does not exemplify any compositions with the claimed gums or proteins. Auweter teaches particles of 200 nm size (col. 3, L 51-56) but not the claimed 80 -120 nm.

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Auweter, EP and Lorant discussed above, fails to teach the claimed moisture content.

Cannalonga teaches vitamin powder preparations comprising emulsifying fat soluble vitamins with water, gelatin and/gum acacia and a sugar or a sugar alcohol, wherein the compositions are dry and free-flowing (col. 1, l 15-20 & col. 2, l 31-43). Cannalonga states that the several factors affect the droplets of vitamin-containing emulsion and that the droplets of vitamin need to be separated from each other for a long time and in order to so, Cannalonga teaches maintaining the moisture content of the composition to permanently establish the formation of particles by loss of water thus preventing agglomeration or coalescence (col. 2, l 57-72). The reference teaches maintaining moisture content to less than 8% (col. 3, l 51-57 & col. 5, example (3% moisture content).

Hence it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the powders of Auweter in nanoparticle size ranges suggested by EP, in the size ranges as low as 30-200 nm (of Lorant) and further maintain the moisture content of the composition to less than 8% or even at 3% because Cannalonga suggests that the low moisture content prevents agglomeration of the particles dispersed. Hence, a skilled artisan would have expected a free-flowing powder with the teachings of Cannalonga.

(10) Response to Argument

Appellants argue that it would not have been obvious to one of ordinary skill in the art to prepare the powders of Auweter in nanoparticle size range suggested by Stein

and further incorporate the size ranges of Lorant because Auweter and Stein are directed to the goal of producing better coloring compositions, and their properties and disclosed particle size of about 200 nm would produce a turbid and colored composition, and Lorant does not remedy these deficiencies. Appellants refer to the declaration of Dr. Bruno and argue that the claimed compositions produce optical clarity.

Appellants' arguments have not been found persuasive because instant claims do not recite the argued feature i.e., "optical clarity". Instead, instant claims are directed to "dry powder" compositions and not any optically clear solutions. If a prima facie case of obviousness is established, the burden shifts to the applicant to come forward with arguments and/or evidence to rebut the prima facie case. See, e.g., In re Dillon, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990). However, arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., In re Huang, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984). In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Additionally, appellants have not shown that colored composition can only result in turbidity and not an optically clear composition. The argument is based on the premise that colored composition should always result in turbidity, when in fact most colored beverages are not turbid and instead clear. In this regard, appellants refer to the instant specification (page 7, l 1-6) and states that fat soluble vitamins tend to increase the turbidity when added to beverages". However,

appellants have not provided any comparative evidence either in the instant specification or in the declaration of Dr. Leuenberger to show that the nanoparticulate fat soluble vitamins of Auweter impart turbidity. The examiner further points that while the argue limitation “optical clarity" is an intended use, the dry powders of Auweter dissolve in water and yield “clear" yellow dispersion in water (see example 1 of Auweter). Therefore, the argument that Auweter and Stein are directed to produce turbid colored compositions is not persuasive. If appellants argue that the turbidity of a 200 nm particle is at a transitional point between visible and invisible range of the spectrum, Auweter teaches 200 nm particles and still teaches a clear liquid (example 1). Additionally, Appellants have not shown any unexpected advantage with the clarity of the claimed particle sizes. Appellants have not shown how the orange hue imparted by the clear yellow dispersions (in example 1) of Auweter is inferior to the argued "optically clear" composition obtained with the claimed powder particles, particularly when Auweter also teaches a clear dispersion. Similarly, appellants argue that Stein teaches intensive yellow, red, or cherry-red coloration with powder particles of 196-240 nm, without providing any evidence with respect to the clarity of the dispersions.

Appellants argue that the physiochemical properties of beta-carotene and instant claimed fat-soluble vitamins differ in significant ways that affect the goals in formulation, and in looking to formulate a liquid oil to achieve a powder composition having optical clarity, one of ordinary skill in the art would not have looked to technologies formulating a solid, insoluble, colored compound which are for preparing compositions directed to better coloring agents. It is argued that Auweter provides a solid dispersion of beta-

carotene powder in a liquid dispersion stabilized with a colloid, whereas instant composition provides solid droplets of fat-soluble vitamin dispersed in a matrix of emulsion-forming composition, the composition having sufficient emulsion forming properties in an oil-in-water context, to emulsify the oil into a fine dispersion in aqueous medium and forms a stable emulsion of the claimed droplet size. Appellants refer to the declaration of Mr. Herman Stein that states "[d]uring the research that led to the invention disclosed in Stein, my co-inventors and I, using the knowledge available at the time, attempted to produce the smallest possible particle size." It is argued that Stein goes on to assert that "[a]s Example 5 shows, at the time, at best we could produce particle sizes of about 196 nm."

Appellants' arguments are not persuasive because instant claims (except for claims 10 and 11) are not limited to any specific fat soluble vitamin, whereas the combination of references (Auweter and Stein) teaches carotenoids (provitamin A) and both references also teach tocopherol in their examples (vitamin E). Further, both Auweter and Stein are related to preparing fine powder preparation of oil soluble materials that read on the claimed fat soluble materials. Accordingly, it is the position of the examiner the teachings of Auweter and Stein are pertinent and in the same field of the claimed invention. With respect to the claimed particle size, it is to be noted that the instant rejection is not based on the teachings of Auweter or Stein references alone and instead over a combination of Auweter and Stein in combination with Lorant. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 USPQ 871

(CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Lorant teaches particle sizes in the range of 30-200 nm, which includes the claimed range of 80-120 nm.

Appellants argue that one of ordinary skill would not have looked to either Auweter or Stein for new compositions with optical clarity. It is argued that and Lorant teaches a cosmetic or dermatological composition in the form of a gelled ultrafine oil-in-water emulsion and does not remedy the deficiencies of Auweter or Stein to achieve the composition of claim 36. It is argued that Auweter and Stein are directed to carotenoid preparations directed to producing better coloring effects in food, whereas, Lorant is directed to a gelled ultrafine oil-in-water emulsion capable of being obtained by phase inversion, where gelling of this type of emulsion improves its stability for better cosmetic or dermatological compositions.

Appellants' arguments are not persuasive because the following exemplary rationales that support a conclusion of obviousness include: Combining prior art elements according to known methods to yield predictable results; Use of known technique to improve similar devices (methods, or products) in the same way; Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; and Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. KSR, 550 U.S. at ___, 82 USPQ2d at 1396. Thus, even though the teachings of Lorant

are not related to food coloring composition, Lorant teaches preparation of ultrafine particles of oil-in-water emulsions wherein the mean size of the particles that form the fatty phase ranges from 70 nm- 1000nm or more preferably 70-300 nm (col. 6, l 27-33). Lorant teaches that the stability of the oil-in-water emulsions is affected by particle sizes of the dispersed oil droplets, which is in relation with the surface tension between continuous and the non-continuous phase. Lorant teaches that the smaller particle size, lesser the surface tension and higher the stability (see col. 1, l 26-32). According to Lorant reducing the particle size of the oily phase can reduces the need for high concentrations of emulsifying agents and suggests a particle size of 50-1000 nm. Thus, if appellants argue that the claimed particle sizes are important in the context of an oil-in-water emulsion (see page 13, 2nd paragraph of the Appeal Brief), then certainly, Lorant suggests ultrafine particles that includes the claimed sizes for the stability of oily phase in an oil-in-water emulsion. Additionally, Lorant also teaches bluish and virtually transparent emulsion (example 1, col. 10-, l 40-53), the viscosity of which is not modified by the addition of gelling agent (col. 2, l 44-54). Therefore, even though Lorant does not teach edible compositions (such as those taught by Auweter and Stein), one of an ordinary skill in the art would have practiced known techniques of preparing oil-in-water emulsions, of Lorant, in the teachings of Auweter or Stein to arrive at the claimed particle sizes of the oily phase. A skilled artisan would have been motivated to do so in order to achieve stably suspended oily droplets that result in transparent emulsion upon emulsification.

Appellants argue the processes of Auweter and Stein do not provide any guidance as to how to make the instant compositions. It is argued that according the declaration of Dr. Leuenberger, the process of Auweter is different from the instant claimed process (claim 29). It is argued that Auweter teaches solid in a liquid dispersion of fine particles of beta-carotene stabilized with colloids and not the process of using an emulsion forming composition that has sufficient stabilizing properties in oil in water context to form stable emulsion of claimed droplet size. It is argued that the reference teaches 20-80 bar and the instant high pressure (680 bar to 4080 bar). It is argued that according the declaration of Dr. Leuenberger, Auweter does not suggest high pressure and that the literature indicates that pressure is not a result –effective variable in relation to the diameter of particles in an emulsion. According to Dr. Leuenberger, the solvents of Auweter and Stein are different and yield in particles of 200 nm that is much higher than the claimed 80 to 120 nm.

Appellants' arguments are not persuasive because instant claims are directed to a composition and not a method or process of producing the composition. "[E]van though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The patentability of the claimed composition has not been shown to depend on the high pressure

homogenization. Similarly, with respect to the process limitation of claims 29-31 and 33-34, as explained above, the patentability of does not depend on its method of production. On the other hand, Lorant provides the motivation to reduce the particle sizes of oily material (carotenoid of Auweter) to as low as 50 or 70 nm with an expectation to provide stability upon emulsification.

Appellants argue that Cannolonga does not overcome the deficiencies of Auweter, Stein and Lorant and therefore, claim 36 would not have been obvious over the above combination of references. However, appellants' arguments regarding Auweter, Stein and Lorant have been addressed above. Cannalonga also teaches vitamin powder preparations comprising emulsifying fat soluble vitamins with water, gelatin and/gum acacia and a sugar or a sugar alcohol, and hence in the same field of endeavor as Auweter, Stein and EP. Further, Cannalonga teaches maintaining the moisture content of the composition to permanently establish the formation of particles by loss of water thus preventing agglomeration or coalescence. Hence, a skilled artisan would be motivated to reduce the moisture content of the composition of Auweter modified by Stein and EP with an expectation reduce agglomeration and coalescence.

Appellants' arguments with respect to that claims 3-9, Auweter clearly teaches among others fish gelatin (example 1), vegetable proteins and gum arabic, which meet the instant claim limitations. Further, Stein also teaches (page 3, col. 1, l 2-10) vegetable proteins, gum arabic, starch etc. Accordingly, the argument that the above claims are independently patentable is not persuasive. With respect to claims 10 and 11, while Auweter and Stein do not teach the claimed esters of vitamin A or E or K, both

Auweter and Stein teach tocopherol in addition to beta-carotene (example 1 of Auweter and examples of Stein) and additionally both the references teach solubilizing carotenoids, by micronization and preparation of fine particles. Auweter also suggests esters of carotenoids (see col. 4, l 15-24). Accordingly, one of an ordinary skill in the art would be able to employ the process of Auweter to prepare fine particle powders of carotenoids or other forms of vitamin A or its esters in order to achieve higher solubility of the otherwise insoluble compound. While appellants argue that tocopherol of Auweter and Stein is liquid oil, instant claims do not exclude tocopherol (vitamin E). With respect to the argument regarding the ratios of fat soluble vitamin to matrix component, the examples of Stein includes gelatin and beta-carotene in amounts that fall within the claimed ratios (of about 1:99 to about 3:1 or about 1:8 to about 1:1). In this regard, while applicants have not provided any unexpected advantage with the claimed amounts of the matrix components, Auweter teaches suggests 10-50% by weight of protective colloids and 0.5% to 20% by weight of carotenoids (see col. 4, l 53-59). Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ suitable amounts of carotenoids and colloid materials so as to achieve the desired and optimum dispersibility of carotenoid in the protective colloid. With respect to claim 17, Auweter not only teaches powder composition but in general teaches pharmaceutical compositions and therefore preparing a suitable pharmaceutical formulation such as powder, liquid or tablet would have been within the scope of one skilled in the art at the time of the instant invention was made. For claims 28 and 35, Auweter and Stein teach the claimed oil soluble materials and also the

claimed proteins and polysaccharide materials. Auweter also teaches a dispersion of carotenoid powder in aqueous solution of colloid, which should intrinsically result in an emulsion.

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Lakshmi S Channavajjala/

Primary Examiner, Art Unit 1611

Conferees:

/DAVID J BLANCHARD/

Supervisory Patent Examiner, Art Unit 1619

/Robert A. Wax/

Supervisory Patent Examiner, Art Unit 1615